



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,399	08/08/2006	Brian C. Case	3006-1783	3287
30565 7590 01/21/2010 WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP 111 MONUMENT CIRCLE, SUITE 3700 INDIANAPOLIS, IN 46204-5137				
EXAMINER SHARMA, YASHITA				
ART UNIT 3774		PAPER NUMBER		
NOTIFICATION DATE 01/21/2010		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketDept@uspatent.com

### Office Action Summary

**Application No.**

10/551,399

**Applicant(s)**

CASE ET AL.

**Examiner**

YASHITA SHARMA

**Art Unit**

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2, 3, 10, 11, 13, 14, 26-42 and 44 is/are pending in the application.
- 4a) Of the above claim(s) 3, 33-37 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 10, 11, 13, 14, 26-32, 38-40, 42 and 44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 April 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 05/05/2008
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election **without** traverse of group III (claims 2, 10, 11, 13, 14, 26-32, 38-40, 42 and 44) species C (Fig. 5), subspecies b (Fig. 3) in the reply filed on 11/02/2009 is acknowledged. Claims 3, 33-37 and 41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Thus, claims 2, 10, 11, 13, 14, 26-32, 38-40, 42 and 44 are presently pending in this application.
2. The reply to restriction requirement does not include an election of Subspecies 1, 2 or 3 (Figs. 1A-1C). The applicant is required to elect one of the subspecies from Figs. 1A, 1B or 1C in the response to this action.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. **Claims 2, 10, 11, 13, 14, 26-32, 38-40, 42 and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Pavcnik et al. (2009/0157169 continuing from at least 2/5/2001).**
5. Regarding claim 26 and 32, Pavcnik discloses a method for modifying blood flow in a vascular vessel, the method comprising: percutaneously delivering one or more pieces of flexible material having two or more leaflets (covering 45 or leaflets 78, 79; pg. 8, par. 0078) to a site within a vascular vessel (claim 21); and percutaneously attaching at least portions of said one or more pieces of flexible material to walls of the vascular vessel (claim 17) so as to form a structure that selectively permits blood flow in a first direction and resists blood flow in a second direction (claim 21).
6. Regarding claims 27-31, Pavcnik discloses the flexible material has remodelable properties, contains collagen (pg. 8, par. 0078), comprises an extracellular matrix material containing collagen and submucosa (pg. 5, par. 0067).
7. Regarding claims 38-40, Pavcnik discloses percutaneously delivering comprises deploying the flexible material from a lumen of a percutaneously advancable device (catheter or balloon; claims 17 and 18), deploying a delivery structure from the lumen, the delivery structure including the flexible material releasably held to an expandable element (par. 4, par. 0060; claims 18 and 19), wherein the expandable element includes a balloon (claim 17).
8. Regarding claim 42, Pavcnik discloses the attaching includes attaching a band of said flexible material in a path extending at least partially longitudinally and at least partially circumferentially along the wall (as best shown in Figs. 48 and 49).

9. Regarding claim 44, Pavcnik discloses attaching edges of said one or more pieces of flexible material to walls of the vascular vessel (Figs. 48 and 49; pg. 8 par. 0078).
10. Regarding claims 2, 13 and 14, Pavcnik discloses the edges have a plurality of structural elements for attaching to said walls, wherein the elements are barbs 124 (Fig. 43) (claim 17).
11. Regarding claims 10 and 11, Pavcnik discloses the edges have reinforced edges and a thickness greater than a central portion of said one or more pieces of flexible material (pg. 8, par. 0078) (Fig. 45). Pavcnik discloses "other layers of different materials can be laminated to or blended with the edge portion to provide desired properties," which allows for the reinforced edges that are thicker than the central portion of the flexible material. (pg. 8, par. 0078)

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YASHITA SHARMA whose telephone number is (571)270-5417. The examiner can normally be reached on Monday - Thursday, 8 am to 4 pm EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Y. S./  
Examiner, Art Unit 3774  
/Thomas J Sweet/

Primary Examiner, Art Unit 3774